GUIDANCE FOR SHARING OF DATA AND RESOURCES GENERATED BY THE MOLECULAR LIBRARIES SCREENING CENTERS NETWORK (MLSCN) - ADDENDUM TO RFA RM-04-017

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National Institutes of Health (NIH)
(http://www.nih.gov/)

This Notice is for a roadmap initiative. All NIH Institutes and Centers participate in roadmap initiatives.

This addendum to RFA-RM-04-017, "Molecular Libraries Screening Centers Network (MLSCN)" (http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-04-017.html), which was released in the NIH Guide for Grants and Contracts on April 21, 2004, provides further information about the NIH guidance relevant to sharing of data from, and the management of intellectual property (IP) related to resources generated by the pilot MLSCN centers. The MLSCN was described in detail in RFA-RM-04-017, including NIH's programmatic interest in having assay protocols, screening data, and optimization chemistry for probe development within the MLSCN centers publicly available as rapidly and freely as possible, e.g., minimizing restrictive enforcement of IP. Specifically, the RFA provided preliminary information on NIH's proposed plans for sharing data and research resources generated by the MLSCN centers as well as IP rights and accessibility of research resources. However, the RFA also indicated that the NIH would convene meetings to further discuss IP issues associated with the Molecular Libraries Roadmap, and would issue updated guidance in the NIH Guide prior to the receipt date for RFA-RM-04-017. Since the issuance of the RFA, the Molecular Libraries Roadmap Implementation Group has convened two meetings, received opinions, and discussed these issues with a broad range of chemists, technology transfer experts, and legal advisors from the academic, non-profit, government, biotechnology, pharmaceutical, and disease foundation sectors of the scientific community. Taking these discussions into consideration, NIH has developed this notice to provide the updated guidance for the subject RFA.

Background

The MLSCN is intended to be a national resource that is capable of providing: (a) innovative high throughput molecular screening (HTS) approaches for the identification of small organic molecules (compounds) that are active in biological assays; and (b) synthetic chemistry capabilities to improve the utility of these molecules as bioactive probes for in vitro, and potentially in vivo, studies of normal and abnormal physiology of cells, organs, model systems, and/or organisms. The MLSCN will include the intramural NIH Chemical Genetics Center and the pilot centers that will be funded as a result of RFA-RM-04-017.

NIH's primary objective for this new public sector screening effort are: (a) to identify bioactive compounds that will constitute a new set of research tools to be used by scientists in both the public and private sectors; (b) to facilitate studies of biology and pathophysiology; (c) to catalyze the identification of novel targets for therapeutic intervention. Furthermore, in some cases, the compounds identified by the MLSCN will ultimately serve as starting points for drug discovery programs by the private and public sectors; however, such drug discovery activities are outside the scope of the MLSCN initiative.

The MLSCN will collaborate and interact with several other components of the Molecular Libraries Roadmap Initiative. The first such component is the NIH Small Molecule Repository, which will be a repository of 100,000-500,000 publicly available, chemically diverse, small organic molecules of both known and unknown activities. The compounds in this repository will constitute a National Screening Set and, with one exception, will have no IP restrictions. The exception is that of certain FDA-approved drugs, which may be included in the collection because of their potential for immediate usefulness and benefit to public health. The other Molecular Libraries Roadmap components are PubChem, a public sector database that will archive the chemical structures and biological data generated by the MLSCN, and a program to develop related technologies. See http://nihroadmap.nih.gov/molecularlibraries/index.asp for a more complete description.

Since the inception of the Molecular Libraries Roadmap, NIH has emphasized that, in order to reap the maximum benefit from the MLSCN, the HTS data, assay protocols, and chemical structures of compounds tested in the centers should be publicly available. There are very strong scientific arguments supporting this position.

Small molecule probes that selectively interact with biological targets are extremely valuable research tools for understanding the functions of proteins and biological pathways. A collection of such probes that would allow the comprehensive study of all of the proteins and other gene products encoded by the human genome would be an invaluable contribution to biomedical research.

It will take the combined resources of researchers in the public and private sectors many years to use small molecule probes to characterize the biology of genes and proteins of interest, cellular processes, and disease processes, and then to use that information to develop products and other approaches that will improve public health.

Potentially, the open sharing of data, research tools, and resources will lead more rapidly to the identification and validation of novel targets for drug discovery, and will facilitate the more rapid development of therapeutics by both the private and public sectors, with resulting benefits to public health, especially for rare or marginalized disorders.

Guidance for Community Resources

The following data and materials generated or developed by the MLSCN are expected to be community resources. These include: (1) primary data from high throughput screening (HTS); (2) data generated in secondary screens; (3) protocols for assays implemented in the MLSCN; (4) the chemical structure of compounds tested in the MLSCN; and (5) the synthesis protocols for optimization chemistry for probe development conducted within the MLSCN centers.

Note: Prior to the implementation of assays, the MLSCN will consider whether any existing IP rights restrictions are consistent with the objectives of this initiative.

NIH is concerned that enforcement of patents on HTS hits or chemical probes, could have a chilling effect on the development of future substantive inventions. Such actions could interfere with the broad utilization of early-stage biological and chemical information. In addition, developers might not pursue projects where there is prior patenting. The intention of the MLSCN program is to facilitate subsequent innovations that are at a later stage of development. Stimulation of such subsequent development is the ultimate goal of the MLSCN program.

It is, therefore, NIH's understanding that the usefulness of the data and resources generated by the MLSCN would be of maximal benefit to public health if they are treated as a community resource and made publicly available. While NIH recognizes that, under the Bayh-Dole Act, awardees have the right to elect title to subject inventions and seek appropriate IP protection, the data sharing and IP plans should take all of the above considerations into account. Applicants should provide clear explanations and rationales for any proposed plan that involves principles differing from those described in this Notice.

Guidances for IP and Accessibility of Technology Development Resources

A separate component of the IP plan should address any other data and resources that are expected to be generated by the MLSCN centers. These may include, but are not limited to, HTS methods or instrumentation, development of technology to automate or miniaturize assays for HTS, data analysis software, etc. NIH encourages applicants to consider inclusion of "non-assert" language in IP plans for all potentially patentable inventions to ensure that, while an institution might apply for a patent on an invention, e.g., as a diagnostic or as a measurement tool, the institution would not attempt to enforce that patent against organizations utilizing the technology for research purposes.

Review of Plans

The data sharing and IP plans in the application will be evaluated by the Scientific Review Committee using the principles and expectations detailed in this Notice, but will not be considered in the priority score. Following the review, program staff will

negotiate a final version of plans for data sharing and IP to ensure accessibility of research resources. Finalized plans will be made a term and condition of any cooperative agreement awarded under this RFA.

Applicants' plans for maximizing the public use of the data and resources generated by the MLSCN network will be a major evaluation criterion for the pilot centers, and for applicants to become fully operational MLSCN centers. During the pilot MLSCN period, NIH will solicit opinions and collect additional data from the scientific and commercial sectors to allow an evaluation of whether the approaches described above are sufficient to ensure that screening data and resources generated by the MLSCN centers are broadly available. If the goals of the MLSCN are not being met using this approach, NIH will consider using a determination of exceptional circumstances (DEC) under future awards to restrict or eliminate the right of parties to elect title to subject inventions.

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